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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,005	09/11/2000	Erich Wanker	V0179/7001	1379

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02/23/2005

Helen C Lockhart
Wolf Greenfield & Sacks
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,005

Applicant(s)

WANKER ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 17-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) 13-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction Election

1. Applicant's response file 11/26/04 is acknowledged and has been entered. Claims 21-26 have been cancelled. Claims 27-30 have been added. Currently, claims 1-20 and 27-30 are pending and are under examination.

Rejections Withdrawn

2. In light of Applicant's amendment, the rejection of claims 11 and 17 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.
3. In light of Applicant's amendment, the rejection of claims 1, 6-12, and 18-20 under 35 U.S.C. 102(b) as being anticipated by Mignotte et al. (Mitochondrial DNA-Binding Proteins that bind preferentially to Supercoiled Molecules containing the D-Loop Region of *Xenopus Laevis* mtDNA, Biochemical and Biophysical Research Communications, November 30, 1983), is hereby, withdrawn.
4. In light of Applicant's amendment, the rejection of claims 2, 3, and 5 under 35 U.S.C. 103(a) as being unpatentable over Mignotte et al. in view of Tateishi et al. (Removal of Causative Agent of Creutzfeldt-Jacob Disease through membrane filtration method, Membrane, 1993), and claims 4 and 17 under 35 U.S.C. 103(a) as being unpatentable over Mignotte et al. in view of Tateishi et al. and further in view of Stott et al. (Proc. Natl. Acad. Sci. USA, 1995), are hereby, withdrawn.

New Ground of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-6, 8-12, 17-20, and 27-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Kalchman et al. (WO 97/18825).

Kalchman et al. discussed the role of huntingtin and HIP1 in the pathology of Huntington's disease (HD). Kalchman et al. specifically disclose that the interaction between HD proteins and HIP1 is influenced by the number of polyglutamine repeats and that expanded polyglutamine tracts aggregate into large irregularly shaped deposits in HD brains (see pages 1, 6, and 7). According to Kalchman et al., individuals suffering from Huntington's disease have polyglutamine expansions of at least 35 glutamines, at least 41 glutamines, at least 48 glutamines, or at least 51 glutamines, (36 or greater glutamines) (see page 2). In protein preparation and western blotting for expressions studies, proteins from tissues and cells of human and other mammals were treated with detergent, sodium dodecyl sulphate (separated on SDS-PAGE mini-gels) and HIP1 and huntingtin proteins were captured and detected (transferred and electroblotted) on low protein adsorptivity filter, i.e. PVDF membrane, by Immobilon-P, Millipore. Immunoreactivity was determined using antibodies against HIP1 and Huntingtin and visualized in chemiluminescent ECL solution. Kalchman et al. further determined that

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HIP1 colocalized with Huntingtin in P2 and P3 membrane fractions and that solubilization with non-ionic detergent such as t-octylphenoxypolyethoxyethanol, i.e. Triton X-100, revealed that HIP1 is insoluble to Triton X-100 (see Examples 7 and 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalchman et al. (WO 97/18825) in view of Yanai et al. (US Patent 6,743,432).

Kalchman et al. has been discussed supra. Kalchman et al. differ from the claimed invention in failing to teach using cellulose acetate as filter membrane.

Yanai et al. disclose hydrophilic membranes having low adsorptivity for protein (see Abstract). Yanai et al. teach that cellulose acetate and polyvinylidene fluoride (PVDF) membrane filters have low adsorptivity for proteins (see column 3, line 58 to column 4, line 38 and column 5, lines 12-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute cellulose acetate membrane filter as taught by Yanai for the PVDF membrane filter used in the method of Kalchman because Yanai specifically showed that cellulose acetate membrane filters constitute obvious variations of low protein adsorption filters, which are known and routinely varied in the art.

Response to Arguments

7. Applicant's arguments with respect to claims 1-12, 17-20, and 27-30 have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

8. Claims 13-16 are clear of the prior art of record. Claims 13- 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach or fairly suggest a fusion protein for use in the method of claim 1, comprising 1) a (poly)peptide that enhances solubility or prevents aggregation of the fusion protein; 2) an amyloidogenic (poly)peptide that self assembles into amyloid-like fibrils or protein aggregates when released from the fusion protein; and 3) a cleavable site that separates 1) and 2) of the fusion protein; and wherein the fusion protein is further incubated with a suspected inhibitor of amyloid-like fibrils and protein aggregate formation, and simultaneously or concurrently, with a compound that induces cleavage at the cleavage site.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

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272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
February 11, 2005 *GR*

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641
2/11/05